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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,345	09/16/2003	Levon Arakelyan	Q71975	2068

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

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09/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/662,345	**Applicant(s)** ARAKELYAN ET AL.	
	Examiner LORI A. CLOW	**Art Unit** 1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 August 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): Rejections under 35 USC 101 with regard to claims 1-14 only.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *1-9,11 and 13-21*.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: *10 and 12*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Lori A. Clow/
Primary Examiner, Art Unit 1631

Continuation of 11. does NOT place the application in condition for allowance because: The newly recited claim amendments are entered herein. However, the instant application is not in condition for allowance, as claims 15-21 remain rejected under 35 USC 101 for the reasons set forth in the previous Office Action and re-iterated below. In addition, the newly recited claim limitations to claims 1-9, 11, and 13-21 raise new issues under 35 USC 112, 2nd paragraph, as indicated below.

35 USC 101
Claims 15-21 are drawn to a method for a method of performing interactive clinical trials for testing a new drug in which the method comprises obtaining data from pre-clinical trials in a computer model and performing computer simulations using a computer model.
In accord with the decision in In re Bilski (cited below), a claim to a process or method must meet the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (Gottschalk v. Benson, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus or (2) transforms a particular article to a different state or thing.
In the instant case, the method claims are not so tied to another statutory class of invention because the method steps that are critical to the invention are "not tied to any particular apparatus or machine" and therefore do not meet the machine-or-transformation test as set forth in In re Bilski 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). The instant rejection could be overcome by amending the claims to performing said method steps in a "suitably programmed computer" or other such claim language, provided support is found in the Specification as originally filed.
Applicant argues that the Examiner indicated that the claimed invention involves a "transformation" that satisfies the transformation prong of the "machine-or-transformation test required by Bilski and that the Examiner undetstood that although the presently claimed method involves a mathematical algorithm, the algorithm is used to transform the data obtained in vitro or in vivo from a pre-clinical or clinical phase to provide an optimal treatment protocol obtained by an interactive clinical design"
This is not persuasive. The Examiner respectfully disagrees with the characterization of the interview discussion regarding In re Bilski. The Examiner stated in the Interview that it was, in regard to claim 1 (and those claims dependent therefrom) the step of "performing a phase I clinical trial in which a clinical trial on at least a single dose of the drug of (a) is administered to at least one human" that provided the "transformation" as required under Bilski. It is the physical step of "administering" a drug to a human patient that meets the transformation prong of the test. The Examiner did not agree that it was the algorithm the transformed data. In fact, no algorithm is claimed herein that performs any such "transformation" step in the claim.
The Examiner further respectfully disagrees with the characterization that In re Bilski does not apply to Applicant's invention. The Examiner directs Applicant to the Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 USC 101 that can be found at http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25_interim_101_instructions.pdf. The Examination Instructions clearly state that a claim to a process, of which is instantly claimed, must pass the machine-or-transformation which ensures that the process is limited to a particular practical application.
Applicant argues that the claimed method involves a practical application of the raw data obtained either in vitro, in vivo, or from actual small clinical trials to provide an optimum treatment regimen or clinical trial design for cancer treatment. Again, with respect to claims 1-9, 11, 13 and 14 this argument is moot because it has been discussed above that these claims, because of the physical transformation recited at step c), meet the M-or-T test and are statutory. However, with respect to claims 15-21, the claims fail to meet the M-or-T test in that neither a transformation takes place nor is a specific machine recited. The step of "obtaining data from pre-clinical trials", for instance, in claim 15, is merely a step of gathering data and is considered pre-solution activity. The step of "obtaining data" from performing a phase I clinical trial is still considered data gathering (claim 16). The performance of a clinical trial herein is not rectied as being drawn to a physical step such as performing a phase I clinical trial wherein a dose-escalation study is perfromed on a human being, for instance. The Specification outlines trials that are done in silico and therefore the instant claims are interpreted as such. The same rationale applies to claims 17-21. Appliant is cautioned that any amendment to the instant claim set must be fully supported in the Specification as originally filed.

35 USC 112, 2nd paragraph
The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claim 1, as amended, recites, "obtaining data for the pharmacodynamics of the drug of (a)". However it is unclear if the data are being obtained for the drug itself or for the model of the drug. Clarification through clearer claim language is requested.

No claims are allowed.